AUTO*THERM ® 395, MODEL ME 395
510(K) SUMMARY

K022458

SEP 26 2002

Submitter's Name: Mettler Electronics Corp.
Address: 1333 South Claudina Street
Anaheim, CA 92805

Telephone: 714-533-2221

Contact: Robert E. Fleming
Director, QA/RA

Date Prepared: July 26, 2002

Device Name:

a. TRADE NAME: Auto*Therm® 395, Model ME 395
b. CLASSIFICATION NAME: Shortwave diathermy
c. COMMON NAME: Shortwave diathermy

Predicate Device:

a. TRADE NAME: Curapuls 419
b. 510(k) Number: K861248

Description of Device:

The Auto*Therm 395 is a shortwave diathermy device that operates at 27.12 MHz. It provides traditional shortwave diathermy therapy using condenser and electromagnetic coil fields in both continuous and pulsed modes of operation. It is suited for all diathermy treatments in both the clinic and the medical practice.

The ME 395 has four wheels for easy transportation between treatment rooms. Two of these wheels have brakes that can be locked to prevent movement during use. The membrane control panel is mounted on top of the unit. It is easily cleaned and contains all the controls and displays for operating the Auto*Therm 395.

The intensity control knob adjusts the output power via an encoder. The power switch is on the upper left side of the unit. Screw holes for attaching the arms are located on the rear of the unit. The sockets for connecting the cables for the condenser and coil applicators and the detachable mains power supply cable including fuses are also located on the back of the unit. The ripcord for the patient emergency-OFF switch passes through a bushing mounted on the back of the unit so that it can be pulled from all directions.

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Device Intended Use Statement:

510(k) Number: TBD

Device Name: Auto*Therm® 395, Model ME 395

Indications for use:

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase in blood flow
4. Increase range of motion of contracted joints.

Comparison of Technological Characteristics Between Auto*Therm® 395, Model ME 395 and Predicate Devices: (see following page)

AUTO*THERM ® 395, MODEL ME 395
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Comparison of Technological Characteristics Between Auto*Therm® 395, Model ME 395 and Predicate Devices:

FEATURE	AUTO*THERM 395	CURAPULS 419
Mains Supply	115 VAC, ±10%, 50/60 Hz 230 VAC, ±10%, 50/60 Hz	110, 127, 220 or 240 VAC 50/60 Hz
FDA Class	II	II
Safety Classification	1 Type BF	1 Type BF
Frequency	27.12 MHz, ±0.6%	27.12 MHz, ±0.6%
Pulse Repetition Frequency (PRF)	70 Hz/350 Hz	15-200 Hz in 10 steps
Pulse Duration (PD)	2 mSec/0.4 mSec	± 400 µSec
HF out continuous	200 W (rms) @ 50 Ω	450 W (rms) @ 70 Ω
HF out pulsed	30 W (rms) 400 W (peak) @ 50 Ω	1000 W (peak) @ 70 Ω
Modes	Inductive & Capacitive	Inductive & Capacitive
Timer	Membrane switch pads Digital Indication (min)	Rocker switch Digital indication (min)
Maximum Time	30 minutes	30 minutes
Output Control	Intensity potentiometer	Intensity potentiometer
Output Display	LED bar graph reflects % contact + 3-digit, 7-segment display of watts	Bar display intensity meter with silk-screened numerals (1-10) around intensity control
Inductive coil electrodes	Yes	Yes
Flexible Induction electrode	Yes	Yes
Capacitive plate electrodes	Yes	Yes
Soft rubber electrodes	Yes	Yes
Configuration	Cabinet-mounted with wheels	Cabinet-mounted with wheels

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2002

Mettler Electronics Corp.
Robert E. Fleming
Director, QA/RA
1333 South Claudina Street
Anaheim, California 92805

Re: K022458
Trade/Device Name: Auto*Therm 395, Model ME 395
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy Device
Regulatory Class: Class II
Product Code: IMJ
Dated: July 26, 2002
Received: July 26, 2002

Dear Mr. Fleming:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

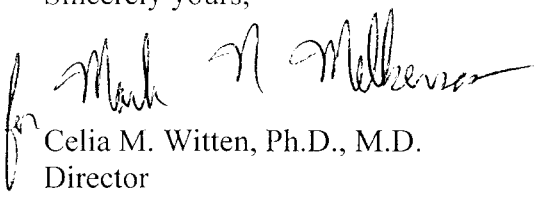
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT
AUTO*THERM® 395, ME 395

Indications for use -

Shortwave diathermy delivers energy in the radio band of 27.12 MHz to provide deep heating therapeutic effects to body tissues. When shortwave diathermy is delivered to the body at intensities capable of generating a deep tissue temperature increase, it can be used to treat selected medical conditions such as:

1. Relieving pain;

2. Reducing muscle spasm;

3. Increasing range of motion of contracted joints using heat and stretch techniques; and

4. Increasing blood flow to tissues in the treatment area.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022458